Application No.: 09/382,615
Filing Date: August 25, 1999
Examiner: D. Shay
Atty. Docket No.: 101327-126

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A maneuverable apparatus for remotely applying therapeutic energy to biological tissue comprising:

a flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending there between;

a deflection member disposed within the first lumen of the flexible elongate member and fixedly attached to said distal end of said elongate member, said deflection member having a proximal end, [and] a distal end, and an inner lumen extending therebetween;

a conductor extending within said [first] lumen of the deflection member for transmitting energy to said distal end of said elongate member, said conductor having a proximal end and a distal end; and

an energy source in communication with said proximal end of said conductor effective to transmit energy through said conductor.

2. (Amended) The apparatus of claim 1, [further including a control handle mounted at the proximal end of said] wherein the deflection member is adapted to be flexed [for flexing said deflection member] longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend.

5. (Amended) The apparatus of claim 1, wherein said deflection member comprises a [second concentric] tubular structure.

9. (Amended) The apparatus of claim 1, wherein said deflection member is [a] non-uniformly shaped, having a tapered narrower [sectionin] section in a region at its distal end.

16. (Amended) The apparatus of claim 15, wherein said second deflection member is [coupled to a control handle for tensing said second deflection member] adapted to be tensioned longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend in a direction opposed to said first deflection member.

17. (Amended) A method for phototherapeutically modulating a target tissue, comprising the steps of:

introducing a flexible elongate member into a predetermined tissue site, said flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween, and a deflection member disposed within the first lumen of the flexible elongate member and fixedly attached to said distal end of said elongate member, said deflection member having a proximal end, [and] a distal end, and an inner lumen extending therebetween;

manipulating said deflection member longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend;

positioning a slidable conductor through said lumen of the deflection member proximate to said tissue site; and

transmitting energy to said distal end of said elongate member through said conductor, such that said target tissue is ablated, coagulated or phototherapeutically modulated without damaging surrounding tissue.

18. (Amended) The method of claim 17, wherein said flexible elongate member is transparent and energy is transmitted through [a] the transparent flexible elongate member.

21. (Amended) A method for treating trabecular tissue, comprising the steps of:

introducing a flexible elongate member proximate to trabecular tissue, said flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween, and a deflection member disposed within the first lumen of the flexible elongate member and fixedly attached to said distal end of said elongate member, said deflection member having a proximal end, [and] a distal end, and an inner lumen extending therebetween;

manipulating said deflection member longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend;

positioning a slidable conductor through said lumen of the deflection member proximate to said trabecular tissue site; and

transmitting energy to said distal end of said elongate member through said conductor, such that said trabecular tissue is phototherapeutically modulated without damaging surrounding tissue.

22. (Amended) A method for treating or preventing atrial fibrillation by ablation, coagulation or phototherapeutic processes, comprising the steps of:

introducing a flexible elongate member proximate to atrial tissue, said flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween, and a deflection member disposed within the first lumen of the flexible elongate member and fixedly attached to said distal end of said elongate member, said deflection member having a proximal end, [and] a distal end, and an inner lumen extending therebetween;

manipulating said deflection member longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend;

positioning a slidable conductor through said lumen of the deflection member proximate to said atrial tissue site; and

transmitting energy to said distal end of said elongate member through said conductor, such that said atrial target tissue is ablated, coagulated or phototherapeutically modulated without damaging surrounding tissue, thereby treating or preventing atrial fibrillation.

23. (Amended) A maneuverable apparatus for remotely applying therapeutic energy to biological tissue comprising:

a flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending there between;

a deflection member disposed within the first lumen of the flexible elongate member and fixedly attached to said distal end of said elongate member, said deflection member having a proximal end, [and] a distal end, and an inner lumen extending therebetween;

a conductor extending within said first lumen of the deflection member for transmitting energy to said distal end of said elongate member, said conductor having a proximal end and a distal end;

an energy source in communication with said proximal end of said conductor effective to transmit laser energy through said conductor;

a reflectance sensor for measuring intensity of light reflected from said tissue while illuminating said tissue;

a monitor connected to said reflectance sensor for monitoring changes in the intensity of light reflected from said tissue;

an analyzer connected to said monitor for determining the degree of therapeutic treatment based upon said monitored changes in said tissue; and

a controller connected to said analyzer and laser for controlling the output of said laser in response to said reflected light from said treated tissue.

24. (Amended) A method for treating or preventing atrial fibrillation by ablation, coagulation or phototherapeutic processes, comprising the steps of:

introducing a flexible elongate member proximate to atrial tissue, said flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending therebetween, and a deflection member disposed within the first lumen of the flexible elongate member and fixedly attached to said distal end of said elongate member, said deflection member having a proximal end, [and] a distal end, and an inner lumen extending therebetween;

manipulating said deflection member longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend;

positioning a slidable conductor through said lumen of the deflection member proximate to said atrial tissue site;

transmitting laser energy to said distal end of said elongate member through said conductor;

measuring the intensity of light reflected from said target tissue; and

controlling the energy applied to said site in response to monitored changes in the intensity of said light reflected from said target tissue, thereby treating or preventing atrial fibrillation.

REMARKS

Claims 1-24 are pending and stand rejected.

Applicants amend claims 1, 2, 5, 9, 16-18, and 21-24. Independent claims 1, 17, and 21-24 are amended to state that the deflection member is disposed within the first lumen of the flexible elongate member. Claims 1, 17, and 21-24 are further amended to state that the deflection member includes an inner lumen extending between the proximal and distal ends thereof, and that the conductor extends within the lumen of the deflection member. Support for these amendments can be found throughout the specification at, for example, page 16, lines 406-418. Claims 2 and 16 are amended to remove the language relating to the control handle, and to state that the deflection member is adapted to be flexed. This amendment is intended to clarify the claim language. No new matter is added. Claim 5 is amended to clarify the claim language by removing the words "second concentric." Claim 9 is amended to correct a typographical error, namely to replace "sectionin" with "section in." Claim 18 is amended to clarify that the flexible elongate member is transparent and energy is transmitted through the transparent flexible elongate member. No new matter is added by these amendments.

Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

Objection to the Drawings

The Examiner objects to the drawings pursuant to 37 C.F.R. 1.83(a). Specifically, the Examiner states that the control handle, as recited in claims 2 and 16, must be shown in the drawings or the feature must be cancelled from the claims. Accordingly, Applicants amend claims 2 and 16 to remove the control handle.

Rejections under 35 U.S.C. §112

Claims 5, 9, and 18 stand rejected pursuant to 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that it is unclear in claim 5 which structure the second tubular structure is to be concentric with. Applicants remove the language "second concentric," and thus claim 5 recites a deflection member that comprises a tubular structure. The Examiner states that the language "sectionin" in claim 9 is unclear. Applicants amend claim 9 to correct this typographical error. The Examiner rejects claim 18, but does not specifically state any reasons for the rejection. Applicants, however, amend claim 18 to more clearly recite that the flexible elongate member is transparent.

Rejections under 35 U.S.C. §102

Claims 1-6, 9, 15, 17-20, and 23 stand rejected pursuant to 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,104,392 of Kittrell et al. (Kittrell). The Examiner rejects claim 21 as being anticipated by U.S. Patent No. 4,985,028 of Isner et al. (Isner). Claims 21 and 22 are rejected pursuant to 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,549,109 of Samson et al. (Samson).

Applicants submit that none of the cited references teach, or even suggest, the present invention. Independent claims 1, 17, and 21-23 each recite a flexible elongate member having a proximal end, a distal end, and a first lumen extending therebetween. A deflection member is disposed within the first lumen of the flexible elongate member and is fixedly attached to the distal end of the elongate member The deflection member includes a proximal end, a distal end, and an inner lumen extending therebetween. An energy conductor extends through the lumen of the deflection member. The claimed apparatus is essentially a tube within a tube with the inner tube serving as the deflection member. None of the cited references teach or suggest such a deflection member having an inner lumen.

Kittrell is directed to a laser catheter having an optical fiber disposed within a catheter for delivering a laser beam intravascularly. The catheter includes a control *wire* affixed *near* the distal end for changing the position of the distal tip. The "deflection member" is merely a solid guide wire. Thus, Kittrell does not teach a deflection member having an inner lumen formed therein, much less having a conductor extending within the inner lumen of the deflection member. Moreover, Kittrell does not teach a deflection member fixedly attached to the distal end. Rather, the distal end includes a distal tip, the guide wire terminating at a location proximate to the distal tip. Accordingly, claims 1, 17, and 23 are not anticipated by Kittrell. Claims 2-6, 9, 15, and 18-20 are allowable over Kittrell at least because they depend from an allowable base claim.

Similarly, Isner is directed to a catheter having an optical fiber disposed therein. A fixation wire and control mechanism are provided for controlling the distal end of the catheter. The fixation wire does not include an inner lumen, and thus does not include a conductor, e.g. an optical fiber, disposed within an inner lumen of the guide wire. Accordingly, claim 21 is not anticipated by Isner and therefore is allowable.

Samson also fails to teach the present invention. Samson is directed to a catheter having a guide wire disposed therein. The guide wire is formed from insulated conductive wires or filaments braided or woven together, and attached at the distal end to sensors. In use, the guide wire is adapted to map electrical activity. Samson does not teach any type of deflection member or control device, much less a deflection member having an inner lumen formed therein. Accordingly, claims 21 and 22 are not anticipated by Samson.

Rejections under 35 U.S.C. §103

Claims 7-12, 15, and 16 are rejected pursuant to 35 U.S.C. §103 as being obvious over Kittrell in combination with U.S. Patent No. 5,306,245 of Heavan. The Examiner argues that Kittrell teaches the device as claimed except for the particular deflection member recited in

claims 7-12, 15, and 16. The Examiner relies on Heaven to teach a deflection member having a cut out portion and, when viewed in profile, an hour glass shape. The Examiner argues it would have been obvious to employ the deflection member of Heaven in the device of Kittrell since Kittrell envision a wide variety of deflection mechanisms.

Applicants respectfully disagree. A person having ordinary skill would not combine Heaven with Kittrell. However, even if the references were combined, the combination does not teach the present invention.

Heaven is directed to steerable catheter which is adapted to receive a medical device. The catheter includes a cut out portion or articulating portion for bending the tubular member. A guide wire is disposed along the outside of the catheter for applying force to the catheter to cause the catheter to bend at the cut out portion. Heaven does not teach or even suggest a steerable apparatus for applying therapeutic energy to tissue, e.g. a steerable ablation instrument. Heaven does not even suggest using the catheter with an ablation instrument. Accordingly, a person having ordinary skill in the art would not combine the steerable catheter of Heaven with the steerable ablation instrument of Kittrell. Moreover, Kittrell already provides a steering mechanism, and therefore a person having ordinary skill in the art would not rely on Heaven to provide a steering mechanism.

Even if Heaven and Kittrell were combined, the combination does not teach the present invention. As previously stated, Kittrell is merely directed to a guide wire disposed within a flexible tube. Kittrell does not teach a deflection member having an inner lumen formed therein, or having a conductor extending therethrough. Heaven does not remedy the deficiencies of Kittrell. The "deflection member" of Heaven is the flexible elongate member, and thus Heaven does not provide a deflection member disposed within a flexible elongate member. Heaven does provide a protective sheath disposed over a portion of the flexible elongate member, however the sheath is only disposed around the cut out portion (Col. 6, lines 12-15). Accordingly, neither reference teaches a flexible elongate member having a deflection member disposed therein, and having a conductor element extending through the inner lumen

of the deflection member. Rather, the combination of Heaven and Kittrell would result in an ablation instrument, as taught by Kittrell, disposed within a steerable catheter, as taught by Heaven.

The present invention provides a novel, non-obvious steerable ablation instrument having a single deflection member disposed within a flexible elongate member. The deflection member, e.g. inner tube, does not require the use of a guide wire for applying a force to the instrument to bend the instrument, but rather is the "guide wire" which is used to bend the flexible elongate member. None of the cited references, either alone or combined, teach or suggest the present invention. Accordingly, claims 7-12, 15, and 16, as well as claims 1-6, 13-14, and 17-24, are allowable.

The Examiner further rejects claims 13 and 14 as being unpatentable over Kittrell combined with Heaven as applied to claim 12, and further in view of U.S. Patent No. 5,129,895 of Vassiliadis et al. (Vassiliadis). The Examiner relies on Vassiliadis to teach the use of a gold coating. For all of the aforementioned reasons, Applicants submit that claims 13 and 14 are not obvious in view of Kittrell combined with Heaven. Vassiliadis does not remedy the deficiencies of Kittrell or Heaven. Vassiliadis is directed to a fiber optic probe for use during a laser sclerostomy procedure. Vassiliadis is unrelated art, and does not provide any type of steering mechanism, or even teach an ablation instrument. Accordingly, claims 13 and 14 are not obvious in view of Kittrell, Heaven, and Vassiliadis, and therefore are allowable.

Claim 24 is further rejected as being obvious over Samson combined with Kittrell. Samson is directed to a catheter for mapping electrical activity. Samson does not teach or suggest a deflection member disposed within a flexible elongate member and having a conductor extending therethrough. Accordingly, Samson does not remedy the deficiencies of Kittrell, and therefore claim 24 is not obvious in view of the cited art.

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 1-24 are in condition for allowance. A clean version of the pending claims is attached hereto. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with Examiner Shay is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

Date: Oct. 15, 2001

Lisa J. Michaud
Reg. No. 44,238
Attorney for Applicants

NUTTER, McCLENNEN & FISH, LLP
One International Place
Boston, MA 02110-2699
Tel: (617) 439-2550
Fax: (617) 310-9550